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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,218	01/18/2001	Markus Haller	P-9417	7371

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MEDTRONIC, INC.  
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EXAMINER
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PRIETO, BEATRIZ

ART UNIT	PAPER NUMBER
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2142

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/765,218

Applicant(s)

HALLER ET AL.

Examiner

Prieto B.

Art Unit

2142

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2005.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-29 and 31-33 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 26 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/02  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

1. This communication is in response to Amendment/RCE filed 06/21/05, claims 1, 16, 31-33 have been amended, claim 30 has been canceled, claims 1-29, 31-33 remain pending.
2. Claim 31 as amended obviate objection regarding compliance with C.F.R. 1.75 and M.P.E.P. § 608.01(m). Objection is withdrawn.
3. Claims 31-32 as amended obviate rejected under 35 U.S.C. 112, second paragraph raised in previous office action. Rejection is withdrawn.
4. Quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action may be found in previous office action.
5. Claims 1-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell in view of Nappholz in further view of Kroll et. al. (US 5,528,906)

Regarding claim 1, Snell teaches features of the claimed invention, teachings the system/method of Figs. 1-4, comprising:

- an implantable medical device (IMD) (16) implanted with the body of a patient (col 4/lines 10-15);
- the IMD being capable of bi-directional communication with a communication module (10) located outside the patient's body (col 7/lines 16-25, 43-56), adapted to establish a communication with the IMD via a communication protocol (7/lines 43-59);
- a remote communication system (12 of Fig. 1);
- a wireless communication system adapted to establish a bi-directional communication with the remote computer system (col 5/lines 2-36, 51-65) over a wireless communication medium (col 9/lines 45-55); however Snell is silent regarding the use of a mobile telephone;

Nappholz teaches a system/method related to medical devices, including a cellular telephone (14 of Fig. 5) (col 2/line 66-col 3/line 9, col 5/lines 20-25) communicatively coupled to a communication module and configured to send and receive information (col 2/lines 46-52 and col 4/lines

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6-25) and further communicate with a remote computer system (27) (col 4/lines 6-25) via cellular telephone and a communication system (26) (col 4/lines 6-11);

a communication cellular system (26) adapted for establishing bi-directional communication with the mobile telephone (14) and the remote computer system (27) (col 2/lines 66-col 3/line 20, col 4/lines 6-25) and the mobile phone and the IMD (col 2/lines 66-col 3/line 20, over a cellular telephone network col 13/line 47-56-col 14/line 30); a communication cellular system (26) adapted for establishing a bi-directional communication between other mobile telephones ("pair of mobile telephones") holding private conversations (col 4/lines 6-25);

communication module (14) comprising a mobile telephone for establishing a bi-directional (link of Fig. 1) communication with the IMD (col 4/lines 6-9) and establish communication bi-directional with the remote computer system (27) (col 4/lines 6-25);

wherein the communication module has means for storing over time-collected patient related information "mining patient history" (col 7/lines 8-19, col 8/lines 19-28, 44-48 and col 15/lines 60-65);

however Snell and Nappholz are silent with respect to generating invoices;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Snell for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings on Nappholz for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, would be readily apparent. Motivation would be to alert patients condition to a health care provider or facility and provide remedial response if required, including corrective therapy, curative, first-aid, etc). Further, given the same suggestions of the Snell reference, the teachings of Kroll for providing a invoice generation mechanism related to services provided by medical devices would be readily apparent, one would be motivated given the mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data from a remote location over a model, to generate invoices in the Snell's system for transmission to remote

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locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

Regarding claim 2, invoice generation means are incorporated into the communication system, for example communicatively connectable to the medical device for receiving information therein (Kroll: col 3/lines 21-43).

Regarding claim 3, invoice generation means are incorporated into a telephone system included in the communication system (Kroll: col 7/lines 5-16).

Regarding claim 4, system of claim 1, further comprising means for electronically transmitting generated invoices to at least one predetermined location for further processing and billing (Kroll: col 4/lines 7-14).

Regarding claim 5, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the number, type or frequency of services provided to the patient by the system (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 6, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the type or identification indicia stored in communication module or IMD (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 7, wherein the remote computer system further comprises means for making a remote diagnostic assessment of the patient's condition on the basis of the information relayed thereto by the IMD or the communication module (Nappholz: col 13/line 47-col 14/line 36).

Regarding claim 8, although Kroll teaches generating an invoice on the basis of the information relayed by the IMD, it does not teach invoice generation in response to a diagnostic assessment;

Official Notice (see MPEP § 2144.03 *Reliance on "Well Known" Prior Art*) is taken that health care providers and services including health management organization that provide means for quantitatively analyze said providers and services was old and well known in the art. For example and not limited to, the Dang reference (US 5,835,897) discussed as prior art, a medical reimbursement computer system including means (computer implementation) of estimating health care services/consumption through the use of diagnostic and patient's illness data relationships and computing or calculating the

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amount of payment to the health provider. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include means for generating an invoice based on a statistical diagnostic assessment which minimizes variances, motivation would be to automatically further determine an expected cost of treatment based on obtained diagnostic.

Regarding claim 9, wherein the remote computer system further comprises means for remotely executing a remedial response or therapy on the basis of the information relayed thereto by at least one of the IMD and the communication module (col 13/line 47-col 14/line 36.)

Regarding claim 10, this claim is substantially the same as claim 8, thereby same rationale of rejection is applicable.

Regarding claim 11, wherein the communication module is incorporated into the mobile telephone (Nappholz: 14 of Figs. 3-4, col 3/lines 1-65 and col 5/lines 20-25).

Regarding claim 13, wherein the IMD and the communication module communicate with one another using radio-frequency telemetry (Nappholz: col 4/lines 6-9, Fig. 2 and col 5/lines 15-19 also Snell: see 14 of Fig. 1).

Regarding claim 14, wherein the means for generating an invoice is incorporated into a wireless network (Nappholz: col 7/lines 23-27).

Regarding claim 15, generating automatic invoices in response to a patient-initiated (Kroll: col 4/lines 31-63).

5. Claims 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll et. al. in further view of Imran (US 4,705,043).

Regarding claim 16, this claim is substantially the same as the combined claims 1, and 11, thereby, same rationale of rejection is applicable. The mobile telephone or the PDA send and receive simultaneously information to and from the IMD over a communication system (Nappholz: bidirectional communication between telephone/PDA and IMD col 13/line 47-56-col 14/line 30); however the above-mentioned prior art does not teach where the bi-directional communication is simultaneously.

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Imran discusses an IMD (1) adapted to communicate with a communication module (2), wherein the IMD is adapted to establish a bi-directional communication with the communication module (col 2/lines 14-20) over a wireless communication system (col 3/lines 34-40), where the bi-directional communication occurs simultaneously in real time (col 1/lines 5-16, col 2/lines 63-col 3/lines 2).

It would have been obvious at the time the invention was made to given the suggestion of Snell for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings of Imran for doing the same would be readily apparent. One would be motivated to incorporate Imran's teachings for establishing a two-way communication link over a wireless communication system among other as suggested and for receiving and transmitting in real-time simultaneously, avoiding the use of wires extending through the patient's skin for monitoring and conducting electrophysiology studies without further surgical implant.

Regarding claims 17-29, these claims are substantially the same as claims 2-13, 14-15, respectively, same rationale of rejection is applicable.

Claim 30 (canceled)

6. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll et. al. in further view of Stutman et. al. (US 5,576,952).

Regarding claim 31, this claim is substantially the same as the combined claims 1, 11 and 16, thereby, same rationale of rejection is applicable. The mobile telephone or the PDA send and receive simultaneously information to and from the IMD over a communication system (Nappholz: bidirectional communication between telephone/PDA and IMD col 13/line 47-56-col 14/line 30); however the above-mentioned prior art does not teach where the bi-directional communication is simultaneously broadcasted, i.e. broadcasting an alert to multiple computers: "remote health care provider", a "remote" computer, and a "remote expert-based" computer system.

Stutman discloses a medical alert distribution system (Fig. 1, 10) for distributing medical information from ambulatory patients (col 4/lines 32-42) to health care providers "subscribers" (col 1/lines 34-45) over a wireless communication network (col 5/lines 20-39), subscriber units may include computers (col 3/lines 20-37, col 4/lines 8-16), distribution comprises broadcasting during a given period to a group of predetermined subscribers (col 8/lines 56-col 9/lines 13).

It would have been obvious to one ordinary skilled in the art at the time the invention was made

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given the suggestions of Snell for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings on Stutman for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, would be readily apparent. One would be motivated to broadcast to multiple different processing devices including computer terminals, portable computers and pagers data from telemetry devices not limited to the one suggested by Stutman, where an independent processes allow efficient operation of the alert distribution system because the processes may perform their function in parallel within the host distributor computer or on separate machines having additional resources.

7. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over NOLAN et. al. U.S. Patent No. 5,404,877 (Nolan hereafter) in view of Kroll in further view of Snell in further view of Stutman et. al. (US 5,576,952).

Regarding claim 32, Nolan teaches substantial features of the invention, including a system (of Fig. 12) further including: an implantable medical device (5) (col 3/lines 28-36); a remote computer system (220 or 260);

the implantable medical device capable of sending/receiving communication with a communication module (240) located external to the patient's body to a remote communication system (220/260) (col 23/lines 65-68 and col 24/lines 14-20);

a cellular/telephonic communicator (240) capable of exchanging information with the communication module (col 23/lines 49-67 and col 24/lines 14-20);

a communication system (Fig. 12) supporting bi-directional communication with the cellular/telephonic communicator (240) external to the patient's body and the remote computer system (260 or 220) (medical device sending to all, i.e. communicator 240 and remote computers (260 & 220) see col 23/lines 65-68 and sending from computer system to medical device see col 24/lines 14-20);

further including a method comprising:

the implantable medical device configured to determine that medical attention should be provided to the patient and provide a warning signal based on said determination (col 2/lines 44-56, col 5/lines 56-60, col 6/lines 60-67, and col 9/lines 10-22, 26-31);

in response to determining that medical attention should be provided sending data from the implantable medical device to the communication module (col 6/lines 60-67, col 9/lines 16-19) for an external remote computer system device;



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remotely analyzing the data (col 24/lines 23-26);

determining on the basis of the analyzed data whether remedial action respecting the IMD is required (col 24/line 26-30);

remotely executing the determined remedial action via the communication system which supports communication to the IMD or patient therein (col 24/lines 33-38), however Nolan is silent with regards to invoice generation means in his system, and further the claimed functions performed by the communication module and those performed by the mobile telephone are performed by one element, (i.e. 240) in the Nolan reference;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63), however Nolan not Kroll teach detecting a remote computer

Snell teaches wherein the communications system is adapted to detect the remote computer system e.g. by means of a transmission protocol involving handshaking (Snell: col 7/lines 43-59).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan of a telephonic communicator external to the patient's body, specifically, communicatively coupled to the IMD for sending/sending data thereto, also having mobile phone capabilities for receiving data from the IMD and establishing a telephonic communication with programmable telephone numbers thereby sending messages over a cellular telephone link to remote computer systems. Nolan teaches that these components although not shown individually (microprocessor and sending/receiving circuitry) are also present in the elements 220 and 230. It would be readily apparent to one ordinary skilled in the art that these component are relocatable being either integrated or distributed, e.g. the separation of the telephonic functionalities and the bi-direction communication circuitry would enable multiple patients at home complex building facility each having telephonic functionality components communicate remotely with their individual health car provider's office via one bi-directional communication circuitry. Furthermore, it would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan for monitoring an implantable medical device on a patient, the teachings of Snell for doing the same, would be readily apparent and the teachings on Kroll for providing monetary reimbursement for medical services provided, including invoice generation mechanism would be readily apparent, one would be motivated given the

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mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data from a remote location over a model, to generate invoices in the primary reference's system for transmission to remote locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

However, the above-mentioned prior art does not teach where the bi-directional communication is simultaneously broadcasted, i.e. broadcasting an alert to multiple computers: "remote health care provider", a "remote" computer, and a "remote expert-based" computer system.

Stutman discloses a medical alert distribution system (Fig. 1, 10) for distributing medical information from ambulatory patients (col 4/lines 32-42) to health care providers "subscribers" (col 1/lines 34-45) over a wireless communication network (col 5/lines 20-39), subscriber units may include computers (col 3/lines 20-37, col 4/lines 8-16), distribution comprises broadcasting during a given period to a group of predetermined subscribers (col 8/lines 56-col 9/lines 13).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings on Stutman for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, would be readily apparent. One would be motivate to broadcast to multiple different processing devices including computer terminals, portable computers and pagers data from telemetry devices not limited to the one suggested by Stutman, where an independent processes allow efficient operation of the alert distribution system because the processes may perform their function in parallel within the host distributor computer or on separate machines having additional resources.

Regarding claim 33, this method claim is substantially the same as claim 32, thereby, same rationale of rejection is applicable.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll in further view of OTSUKA, Ideal state of high density packing view from wiring technology from human brain to LSI and electronic packaging on circuit boards.

Regarding claim 12, however the above-mentioned references do not teach a mobile telephone comprising a PDA.

Otsuka teachings the integration of separate electronic communication components, such as a mobile telephone and a PDA. It would have been obvious to one ordinary skilled in the art at the time the invention was made to further integrate separate application, e.g. PDA to the Nappholz system presently integrating the functionalities of a programmable device and a personal computer application configured for receiving/transmitting telemetry data, with cellular telephone technology, for taking the applied reference teaching a step further, using the advantages of LSI technology and further incorporate a PDA, the size of a card, motivation would be to further provide the patient a more user friendly/portable device that existing prior arts as suggested by the Nappholz reference.

**Citation of Pertinent Art:**

9. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Copies of Non-Patent Literature documents cited will be provided as set forth in MPEP§ 707.05(a):

**US 5,675,371**

Barringer discusses existing cellular telephone industry transmitting data via the cellular telephone network, using the Advanced Mobile Phone System (AMPS) cellular telephone network, which combines "Cellular" and "telemetry" technology. Cellemetry communicates over a communication system, over a 800 MHz cellular control channel frequencies to the Mobile Telephone Switching Office (MTSO) where the data is separated from other (voice) telephone registration information. The data is then sent by landline modems to a central monitoring station.

**US 6,651,104**

Moon discusses existing bus system supporting communication between portable hands free units over the system bus serial port using a defined interface protocol. Future system buses in addition to supporting these accessories will be required to support a serial communications interface to a computer, such as a PC, laptop, or PDA. His invention relates to system bus architectures for cellular telephones, and more particularly, to a multi-level interface for interconnecting a system bus line with application programs located internally or externally of a cellular telephone.

**US 4,972,479**

Tobias, Jr. et. al discloses a cellular telephone system (10 of Fig. 1) includes a plurality of standard cellular telephones, e.g. cellular telephone 12. Cellular telephone 12 communicates with a standard cellular telephone system cell site (20) over a bidirectional radio link indicated schematically at 22. Cell site 20 includes transmitting and receiving circuitry to permit full duplex communication with cellular telephone 12. Cell site 20 is connected to a mobile telephone switching office (23) by well-known means 22 such as leased four-wire telephone lines, fiber optic cable, or microwave links. Mobile telephone switching office 23 provides connections from the cellular system to the public switched telephone network by well-known means 24 (which again may be leased four-wire telephone lines, fiber optic cable, etc.) and the local telephone company central office switch 26.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prieto, B. whose telephone number is (571) 272-3902. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Andrew T. Caldwell can be reached at (571) 272-3868. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, status information for published application may be obtained from either Private or Public PAIR, for unpublished application Private PAIR only (see <http://pair-direct.uspto.gov> or the Electronic Business Center at 866-217-9197 (toll-free).

Any response to this action should be mailed to:

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(571) 273-8300 (New Central Fax No.)

Or Telephone:

(703) 306-5631 for TC 2100 Customer Service Office.

B. Prieto  
TC 2100  
Primary Examiner  
July 28, 2005

  
**BEATRIZ PRIETO**  
**PRIMARY EXAMINER**